



Steven C. Anderson, CAE

President and
Chief Executive Officer

September 9, 1999

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Dockets Management Branch (HFA-305)
Docket No.s 98N-1230 and 98.045N2
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir or Madam:

The National Restaurant Association appreciates the opportunity in this written statement to submit its views on the Food Safety and Inspection Service's (FSIS) and the Food and Drug Administration's (FDA) proposed *Egg Safety Action Plan* [Docket No's 98-045N2 and 98N-1230, Federal Register: August 13, 1999, Vol 64, No. 156, pages 44195 to 44196]. As the leaders of the hospitality industry, we have had a long-standing commitment to food safety and the protection of our customers—and are deeply interested in furthering improvements in the nation's food supply.

Founded in 1919, the National Restaurant Association is the leading business authority for the nation's \$336 billion restaurant industry, which has more than 810,000 restaurant locations. Our 37,000 members represent more than 170,000 individual fullservice restaurants, quickservice units and cafeterias, institutions, hospitals, universities, and military clubs. We have made multi-billion dollar investments in improving restaurant food safety and developing state-of-the-art food-safety education programs during the past 80 years. In cooperation with state and local health officials, the National Restaurant Association has been a partner in the development of numerous state food-safety regulations, food-safety educational programs and informational materials based upon industry research, current science and Hazard Analysis Critical Control Point (HACCP).

We would like to commend the U.S. Department of Agriculture (USDA) and the FDA for their efforts to solicit comments from the industry and the public on the very important issue of *Salmonella enteritidis* (Se) in eggs. We believe that Se is a common foodborne illness and that responsible actions should be taken to reduce incidences of Se infections from eggs in consumers homes and at the retail level. However, we also believe that careful consideration should be given before taking possibly costly, ineffective and counterproductive actions. For this reason, the National Restaurant Association believes that current egg-industry research and flock-improvement developments should be fully supported by FDA and FSIS in order to support industry-directed improvements from the start.

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The Se-in-egg problem surfaced in 1988 and has since been addressed during numerous government hearings. As a result of this attention, many segments of the industry have implemented effective intervention strategies. In 1991, the FDA identified shell eggs at retail as potentially hazardous foods, advising state and local jurisdictions of this interpretation of the earlier versions of the model-retail codes. Since 1993, and particularly after the 1997 version of the FDA Food Code, states began adopting the FDA Food Code with its more stringent temperature requirements for potentially hazardous foods and shell eggs. Simultaneously, the USDA implemented new Egg Product Improvement Act procedures to reduce the probability that flocks would become infected.

From 1996 through 1998, epidemiological data developed through the Centers for Disease Control and Prevention's (CDC) FoodNet show a 44 percent reduction in human Se infections per 100,000 population. The CDC Salmonella Enteritidis Risk Assessment Report in June 1998 indicates that the implementation of a consistent 45 degrees F ambient-air temperature requirement for eggs from flock to retail may result in an additional 8 percent reduction in human illness. Clearly, the striking 44 percent reduction in Se isolates since 1996 reflects the effective implementation of multiple intervention strategies incorporated at various steps by the industry and local officials.

One of these effective strategies is a strong education campaign in egg-preparation safety. Using the Risk Assessment Report information, a decrease in human illnesses of approximately 4,000 can be expected if this strategy is implemented. Part of that reduction is already realized under current state and local enforcement of the egg-refrigeration requirement. We understand that 38 states have already adopted a 45 degree F ambient-air temperature requirement for shell eggs. The report also indicates an expected contamination rate of 5 per 100,000 Se positive eggs. While these figures do provide a basis for improved regulation, they do not reflect a significant and un-addressed problem necessitating preemption of industry efforts or state and local regulatory authorities—these efforts are clearly having an impact on lowering the incidence of Se. Along with industry members, the FDA and USDA should instead devote their resources toward elimination of the bacteria at the source and providing training for state regulatory officials and consumers.

Control of *Salmonella enteritidis* in eggs must incorporate a broad-based, multi-pronged approach that begins with intervention at the production level. A reduction in the level of Se-contaminated eggs and corresponding incidences of Salmonellosis cannot be expected unless introduction of the microbe at the production level is severely restricted. Consequently, such production-level restriction practices must include principles based on sanitary standard operating procedures (SSOPs), good agricultural practices/good manufacturing practices (GAPs/GMPs), and/or other interventions that may be developed, such as feeds that control Se within flocks or through competitive exclusion.

The National Restaurant Association believes that voluntary SSOPs in conjunction with GAPs/GMPs will present the most feasible intervention strategy for all producers, regardless of size. In conjunction with SSOPs and GAPs/GMPs, a nationwide flock monitoring program, fully funded by the federal government and similar to the system employed by Pennsylvania, must be implemented to obtain firsthand data on Se strains and to assure that suspect eggs are removed or diverted from consumers and retail establishments.

Strategies developed to control post-production growth of Se must be consistent with other requirements that are employed throughout the processing, storage, shipping and distribution chains. Temperature requirements, SSOPs and GMPs employed within the egg industry should be based on the same principles that are incorporated for other potentially hazardous, refrigerated foods in retail. The National Restaurant Association previously commented with respect to the FDA's and FSIS's advance notice of proposed rulemaking on Transportation and Storage Requirements for Potentially Hazardous Foods [Docket No. 95-049A]. The Association believes that any final regulations on Se in eggs should be consistent from farm to table and uniformly incorporate provisions as identified in our previous comments. Furthermore, we believe that certain sections of the Food Code will have to be revised to stay consistent with this proposed regulation. For instance, the Food Code does not exempt shell eggs, treated to destroy all Se, from refrigeration.

The National Restaurant Association is not convinced that a proposed lengthy warning statement regarding safe handling instructions for shell eggs is appropriate: numerous FDA focus-group studies have indicated that consumers generally do not pay much attention to such statements, particularly if they are lengthy. FDA received similar negative consumer comments regarding the length of the original versions of some of the proposed health-claim statements developed under the Nutrition Labeling and Education Act and the FDA Food Code.

On the other hand, the National Restaurant Association supports the use of the statement **"IMPORTANT, Must be Kept Refrigerated"** on consumer and retail packaging for eggs. However, the National Restaurant Association does not believe that warning statements per se should be expected to achieve any significant reduction in the numbers of foodborne illnesses associated with Se.

The federal agencies must rely on the states and locals to control shell-egg temperature requirements, particularly in retail establishments. Again, the ability of states to act against adulterated shell eggs should be emphasized. In support, a 1991 survey conducted by the FDA found that only one state that does not have current embargo authority, an authority the FDA does not have under the Federal Food, Drug and Cosmetic Act for foods in domestic commerce. This authority, with due process, already allows states to immediately remove from commerce any food found to be, or suspected of being, adulterated. The elaborate federal enforcement provisions and the preemptive nature of this proposed regulation will have the net effect of reducing effective state control from egg regulation at retail. If one considers an average of more than 20,000 retail establishments per state, the FDA would have to provide massive new inspection resources to regulate retail eggs in the same manner as they are currently regulated by the states and locals today. Consequently, the FDA and USDA should work with industry and the states to address shell-egg education at retail, rather than preempting state inspection laws and duplicating inspections already conducted by state and local jurisdictions today.

Considering the potential for cross-contamination—consistent with the hazards associated with the consumption of any raw or undercooked source of animal protein—education must play an important role in controlling Se illnesses. The consumer and retail education vehicles already exist in our widely used foodservice training program ServSafe, National Food Safety Education month and The Partnership for Food Safety Education to the National Food Safety Initiative educational efforts. The National Restaurant Association believes that national consumer-and-industry educational campaigns are absolutely imperative and we challenge the FDA and USDA to work with us to expand the existing effective programs to reach more people.

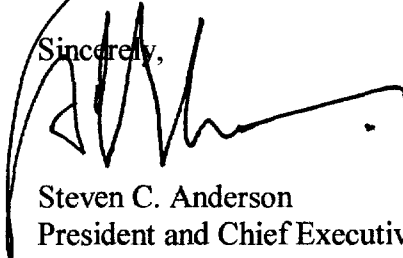
The original advance notice of proposed rulemaking asked if FSIS and the FDA should take a more direct role in regulating restaurants, foodservice operations and retail stores, or if they should continue to rely on the Food Code to provide guidance and encourage state and local authorities to adopt and enforce those standards. We do not believe that the cause of safer food will be served by initiating additional federal oversight of retail egg-storage practices, but rather that responsibility for these matters should remain at the state and local level, as they have for years.

The National Restaurant Association is strongly against the wasteful overlapping of duplicative federal inspections where effective state-inspection programs exist. We strongly encourage the FDA and FSIS to focus federal resources to areas such as transportation-temperature control, egg improvement, local inspector training and certification, accurate illness data, and research and program evaluations. States and localities should continue to be trusted to establish programs for regulating local segments of the food industry. The National Restaurant Association believes that this approach is consistent with the concept of the National Integrated Food Safety System, which should utilize all food-safety resources to provide consumers with the safest food supply available.

Finally, current CDC data—which has shown a significant reduction in Se isolations—do not support an escalating problem, industry inaction or the non-enforcement of retail temperatures by state programs. On the contrary, the CDC data indicates that industry efforts, state and local requirements for the refrigeration of shell eggs, the introduction of new industry technologies and consumer education are having a significant positive impact on the number of Se isolates associated with human illness. These reductions have been maintained during a three-year period, indicating that the reductions are, in fact, real and would probably continue without any federal intervention.

The National Restaurant Association welcomes increased cooperative efforts involving the shell-egg industry, retail, academia and government officials to prepare further training materials and public-service announcements focusing on the safe handling of shell eggs. We appreciate the opportunity to comment on this proposed rulemaking. Should you have any questions or comments, please feel free to call Steven Grover, Vice President, Health and Safety Regulatory Affairs at (202) 331-5986.

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Anderson', with a long horizontal flourish extending to the right.

Steven C. Anderson
President and Chief Executive Officer

cc: Peter Kilgore, Senior Vice President, and General Counsel
Steven Grover, Vice President, Health and Safety Regulatory Affairs

HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CROSS REFERENCE SHEET

Docket Number/Item Code: 98N-1230/C510

See Docket Number/Item Code: 97P-0197/C511
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